Amendment #2
to RFP-NIH-NIAID-DMID-03-09

"New Animal Models for: Part A Tuberculosis (TB) and Part B Invasive Aspergillosis (IA)

Amendment to Solicitation No.:	NIH-NIAID-DMID-03-09
Amendment No.:	2
Amendment Date:	July 29, 2002
RFP Issue Date:	April 29, 2002
Issued By:	Paul D. McFarlane Senior Contracting Officer NIH/NIAID Contract Management Branch 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, Maryland 20892-7612
Point of Contact:	Ross Kelley, Contracting Officer
Name and Address of Offeror:	To All Offerors

The above numbered solicitation is amended to extend the due date for proposals from Monday, August 12, 2002 to Friday, August 30, 2002. In addition, the ATTACHMENT to the RFP entitled PROPOSED DEVIATION TO REQUIRED GENERAL CONTRACT CLAUSES FAR 52.227-11 and FAR 52.227-14 is deleted and replaced with the following:

Notice of Planned Deviations to FAR Clause 52.227-11 Patent Rights - Retention by the Contractor (Short Form) (June 1997) and FAR 52.227-14 Rights in Data - General (June 1987)

NIAID plans to seek DHHS and NIH approval for text deviations to FAR 52.227-11 Patent Rights - Retention by the Contractor (Short Form) (June 1997) and FAR 52.227-14 Rights in Data - General (June 1987). As the standard versions of these clauses will be included in any resultant contracts, these clause deviations will be supplemental to the awarded contracts. The NIAID recognizes the rights of contractors/subcontractors to normally elect and retain title to subject inventions developed under Federally funded contracts, under the provisions of the Bayh-Dole Act. However, to address the Government's present interest in the availability of the new technologies to be developed under contracts resulting from this initiative, the NIAID is invoking the provision of the Bayh-Dole Act at 35 U.S.C. 202 (a)(ii). This provision enables the Government to restrict or eliminate the right to retain title "in exceptional circumstances when it is determined by the agency that restriction or elimination of the [contractor's/subcontractor's] right to retain title to any subject invention will better promote the policy and objectives of [the Bayh-Dole Act]."

Therefore, potential Offerors are advised that a Determination of Exceptional Circumstances (DEC) along with the aforementioned deviated FAR clauses will be sought for this initiative. Because these clause deviations are not yet approved, their text is not available for publication. (However, it is NIAID's intention that the finalized versions of the deviated FAR clauses will be available before award of any contracts resulting from this initiative.) Instead, the following description of how these clause deviations will be practiced under the resultant contracts is provided. Potential Offerors are afforded an opportunity to comment on their understanding of what NIAID is planning and to identify what impact these deviations may have on their conduct of the work should they be awarded a contract.

These planned contracts represent one segment of the Post-genomic Development Program in Tuberculosis (TB) and

Mycology within the Division of Microbiology and Infectious Diseases (DMID), NIAID. This project complements efforts in genome research and model development that are an integral element of NIAID's mission to further basic research in the biology of the microbe, host pathogen interaction and pathology to result in the development of improved vaccine- drug and diagnostic candidates for use in TB and Invasive Aspergillosis (IA). This project is intended to develop and ultimately provide animal model resources to the research community to help translate data ensuing from genomic research into putative candidates for novel preventive and therapeutic strategies. As such, this project is divided into two separate aspects, Part-A dealing with research pertaining to TB, and Part-B pertaining to research in IA. This project first seeks to develop models and research methodologies, and then to make these models and methodologies available to researchers under the contract to enable the in *vivo* validation of putative target genes in a relatively rapid throughput manner, allowing the creation of biological information critical to secure intellectual property claims. The ability to assess biological function of putative target genes in a relatively short time frame while maintaining intellectual property rights to any data ensuing from these evaluations would allow investigators protection of claims as to the suitability of these genes as targets for vaccine and drug development, as well as diagnostics and possibly novel enabling technologies.

Both parts of this contract will develop animal models suitable to answer critical questions in TB or IA research, and will make these models available for the evaluation of biological function of putative gene products. By providing information on biological activity developed under these contracts to suppliers of candidate genes, the NIAID seeks to stimulate research and development in all sectors of the scientific community.

Because the goal of this NIAID post genomic animal model program is to promote the determination of critical biological information, it will be necessary to restrict certain rights of the contractor providing animal model testing to either attract suppliers of proprietary compositions or enable NIAID to offer a package of intellectual property rights to a collaborator for commercialization. It is anticipated that the great majority of genes and ideas submitted to the NIAID for testing will be proprietary in nature, and our experience has demonstrated that suppliers are reluctant to provide new compositions or ideas without complete assurance that their intellectual property rights are protected. In addition to the need to protect third party suppliers' proprietary rights, it is also necessary to consolidate into a single package the intellectual property rights that may arise in the performance of multiple contracts within this NIAID program.

Thus, the NIAID intends to seek a deviation from FAR clause 52.227-11, Patent Rights-Retention by the Contractor (Short Form) (June 1989). Pursuant to a Determination of Exceptional Circumstances (DEC) as required by FAR 27.303, the clause at FAR 52.227-11, Patent Rights-Retention by the Contractor (Short Form) (June 1989) will be modified to restrict the contractor's rights to subject inventions arising under the contract. Specifically, the contractor will be required to assign to the Government or, if deemed appropriate by the NIAID and subject to certain rights reserved to the Government, to a collaborating party designated by the Government the entire right, title and interest throughout the world to each subject invention, except to the extent that rights are retained by the Contractor under the Greater Rights Determination provision of the clause. The contractor may request greater rights to an identified invention, and the NIH will consider whether granting the requested rights will interfere with rights of the Government or any collaborating party or otherwise impede the ability of the Government or others to develop new candidates for therapies, disease prevention and diagnosis as well as potential enabling technologies that may result from data ensuing from evaluations performed under this contract useful for TB and IA. Contractors are encouraged to request greater rights where inventions relate to technology outside NIAID's program and where the contractor has negotiated with a supplier of a proprietary composition for the disposition of patent rights concerning a subject invention related to the composition.

Furthermore, in order to protect the intellectual property rights of third party suppliers, the timing of data publicationwill need to be restricted to allow adequate time for patent applications to be filed on inventions arising from the contracts. This would be accomplished by a deviation from FAR clause 52.227-14, Rights in Data-General (June 1987). Specifically, although NIAID encourages the publication of articles on research results, FAR 52.227-14 Rights in Data-General (June 1987) will be narrowly modified to restrict the Contractor's right to use, release to others, reproduce, distribute, and publish data produced or used by the contractor in the performance of this contract in order to protect the supplier's proprietary rights, to protect data that will be submitted as part of a regulatory filing, and to delay the publication of data as necessary to obtain patent protection. NIAID will reserve the right to coordinate the timing of data publication with the supplier so that appropriate domestic and international invention

applications may be filed. In general, a reasonable delay in publishing is expected to be less than six months.

Responses should be provided (in writing) to the Point of Contact for this RFP. See the bottom of the front page of this RFP for this individual's name and contact information. This comment period expires on the Due Date and Time for receipt of proposals identified in the center of the front page of this RFP.

Except as provided herein, all terms and conditions of the RFP document NIH-NIAID-DMID-03-09 remain unchanged and in full force and effect.

Offerors must acknowledge receipt of this Amendment #2, by the following method:

- By acknowledging receipt of the amendment on each copy of the offer submitted.

Failure to receive your acknowledgment of this amendment may result in the rejection of your offer.

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